Wisconsin Department of Health and Family Services

Pharmacy NewsCapsule

Division of Disability and Elder Services/Bureau of Quality Assurance(BQA) July/Aug/Sep 2004

Hormone Therapy

Ryan Bender Pharm D Candidate, UW Madison

Hormone replacement therapy for women has transformed in the past year because of new data. In May 2003, the Women's Health Initiative (WHI) published data from 16,608 women aged 50 through 79 years who were given 0.625 mg conjugated equine estrogens and 2.5 mg medroxyprogesterone daily. The study investigated the effect of hormone replacement therapy (HRT) on cardiovascular events, stroke, osteoporosis, breast cancer, and colon cancer. The results forced the study to end 3 years early because concerns for safety of the patients receiving HRT.

Of the 8,506 women receiving HRT, 151 had a stroke (1.8%) compared to 107 of 8,102 women (1.3%) in the placebo group. This is a 31 percent increase in relative risk and an incidence of 8 more strokes per 10,000 women taking HRT per year ($p=0.007$). Of the HRT group, 2.9 percent (245 of 8,506) had breast cancer compared to 2.3 percent of the placebo group (185 of 8,102; $p<0.001$). This is a 24 percent increase in relative risk and an incidence of 8 more cases of breast cancer per 10,000 women taking HRT per year. The results also found that per 10,000 women on HRT there are seven more myocardial infarctions and 18 more cases of blood clots in the legs and lungs per year compared to those not on HRT. The study did find some positive effects of HRT: per 10,000 women taking HRT, there were six fewer cases of colon cancer and five fewer hip fractures per year.

The data from Women's Health Initiative Memory Study (WHIMS), a branch of the WHI was published recently in *JAMA*. The study randomized 2,947 women aged 65 to 79 to 0.625 mg conjugated equine estrogen (Premarin) alone or placebo, and 4,532 women to estrogen plus medroxyprogesterone 2.5 (Prempro) or placebo. In the estrogen alone trial, 28 of 1,464 women (1.9%) were diagnosed with probable dementia compared with

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Inside This Issue

Pharmacy Student in BQA

My name is Ryan Bender and I am a pharmacy intern completing a rotation in the Bureau of Quality Assurance (BQA). Until now, I have worked exclusively in the community setting, reviewing prescriptions, counseling patients and talking with doctors and nurses. This internship has allowed me to see a whole new aspect of pharmacy practice. It has taught me the importance of medication pass evaluation and drug use review in the nursing home and assisted living environment.

As I near the end of my seven-week rotation, I would like to thank everyone at the Bureau for making this a positive experience. The skills I have gained here will benefit me throughout my career as a pharmacist.

New Drugs

Ryan Bender Pharm D Candidate

Brand Name	Generic Name	Use
Sanctura	Trospium	Anti-cholinergic for overactive bladder
Caduet	Amlodipine/ atorvastatin	Combination calcium channel blocker and statin (Blood pressure and cholesterol lowering)
Riomet	Metformin	Liquid formulation for type 2 diabetes
Stalevo	Carbidopa/ levodopa/ entacapone	Combination for Parkinson's disease
Vigamox	moxifloxacin	Ophthalmic for bacterial conjunctivitis
Tindamx	Tinidazole	Antiprotazoal for trichomoniasis
Vidaza	Azacitidine	Antineoplastic

Medication Errors

Ryan Bender, Pharm D Candidate
Doug Englebert, Pharmacy Practice Consultant, PRQI

Drug Name Mistakes

LANTUS® (insulin glargine) and LENTE® (insulin zinc suspension)

Lantus® can be confused with Lente® in both verbal and written orders, especially if using the letter L as an abbreviation for Lente®. This is important because the two types of insulin are very different. Lantus® is a long acting product and is dosed every 24 hours, compared to Lente®, which is more rapid and shorter acting. Staff should be aware of the differences and are urged to clarify all orders where L is used as an abbreviation.

As a reminder, insulin is one of the "high risk" medications. High-risk medications may have additional scrutiny placed on them related to ordering, access, etc.

Focus Drug of the Month

Ryan Bender, Pharm D Candidate

Apokyn (apomorphine)

Apomorphine (Apokyn®) is a dopamine receptor agonist approved last April for treatment of Parkinson's disease patients during episodes of hypomobility, which are "off periods" in which the patient becomes immobile or unable to perform activities of daily living. These can occur toward the end of a dosing interval with standard background medications ("end-of-dose wearing off") or at unpredictable times (spontaneous "on/off"). The clinical effect is qualitatively similar to levodopa, and it is usually used as a rescue therapy when the patient becomes somewhat resistant to dopamine replacement.

Apomorphine is given as a subcutaneous injection and is available as 2-ml ampules and 3-ml pen cartridges, both with a concentration of 10 mg/ml. It is critical to understand that doses are expressed in milliliters, not milligrams. To begin a patient on apomorphine therapy, start with 0.2-ml (2 mg) test dose and monitor standing blood pressure closely. If the patient tolerates this without orthostatic hypotension, 0.2 ml may be used PRN for "off"

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19 of 1,483 women (1.3%) receiving placebo. This indicates a 49 percent increase in risk and incidence of 12 more cases of dementia per 10,000 per year, but these results are not statistically significant (p=0.18). When the data from the Premarin group is pooled with the data from the Prempro group, the results are statistically significant. Sixty-eight of 3,693 women (1.8%) taking either product were diagnosed with probable impairment compared with 40 of 3768 women (1.1%) taking placebo. This indicates a 76 percent increase in risk and an incidence of 18 more cases of dementia per 10,000 per year (p=0.005).

The findings from WHI and WHIMS bring health care professionals and patients to the question, "What do we do now with hormone replacement therapy?" The FDA has suggested new labeling that would include information about current approved uses of the drugs: estrogen and combined estrogen with progestin products are effective for treating moderate to severe hot flashes and night sweats, moderate to severe vaginal dryness, and prevention of osteoporosis associated with menopause. The suggested label states that if these products are prescribed solely for vaginal symptoms, health care providers are advised to consider the use of topical vaginal products. The suggested label recommends that if the products are prescribed for osteoporosis, women should be at significant risk for osteoporosis and non-estrogen treatments should be considered inappropriate.

The FDA is advising women and their health care providers that hormone therapy has never been approved for prevention of cognitive disorders such as Alzheimer's disease or memory loss. In an update on HRT for post-menopausal women, the FDA says that although these findings are statistically significant, the risks to individual women are small.

In summary, patients should be informed about the actual risks associated with HRT. Women seeking relief from severe menopausal symptoms should not be very concerned about the increased incidences of stroke, breast cancer, heart attacks, and blood clots if the therapy is short-term. It is important to note that patients who have a history of stoke, breast cancer, heart attacks and blood clots are at greater risk and should not receive HRT. The FDA advises women to talk with their health care providers, and if they decide that hormone therapy is appropriate, they should use the lowest effective dose of for the shortest duration to reach treatment goals.

episodes, increasing 0.1 ml every few days as tolerated. Maximum dose is 0.6 ml (6 mg) up to five times per day as needed. If patient does not use apomorphine for >7 days, restart them at 0.2 ml.

The onset of the "on period" is usually within 10 minutes and lasts for up to two hours. Clinical trials show an average reduction of 49 percent in time spent in the "off" phase.

Patients should be monitored for side effects, the most common being injection site reactions. Rotating injection sites on the stomach, upper arm and thigh can minimize them. Also monitor proper subcutaneous injection technique and sharps disposal.

Apomorphine can cause severe nausea and vomiting, so it is important to treat the patient with trimethbenzamide, an antiemetic, 300mg three times daily starting 3 days before start of therapy and continuing for at least 2 months. 5-HT_3 antagonists (Zofran® and Kytril®) are contraindicated.
Patients should also be monitored for orthostatic hypotension and hallucinations.

If there are medications you would like featured in this column, please send an email to Doug at engleda@dhfs.state.wi.us

Consultant's Corner

Doug Englebert *Pharmacy Practice Consultant PRQI*

This section will appear in each issue and will contain information that will answer your questions. If there is a topic about which you want more detailed information, please drop me an email at engleda@dhfs.state.wi.us and I'll research the topic.

Question 1: Can Lantus® be mixed with other insulins and given in the morning?

Lantus® (insulin glargine) can NEVER be diluted or mixed with other types of insulin. Lantus mixed with other insulins could make Lantus ineffective and painful upon injection. If Lantus is mixed with another insulin, it should be discarded.

Lantus is a long-acting insulin that provides relatively constant plasma concentrations over 24 hours. When the drug was studied and approved, it was given at bedtime. Since it is dosed every 24 hours, it is not clinically necessary to give at bedtime as long as it is consistently dosed at the same time every day.

Question 2: As a surveyor how do we address a resident in a nursing home who administers an inhaler incorrectly?

If you observe an inhaler administered incorrectly by a resident, you need to see if staff is aware that incorrect administration is occurring. If they are aware, have they addressed this in their assessment and on going monitoring of self-administration by that resident? If they have not, you must continue investigating and consider citing F Tag 176 for Self-Administration. We would not cite at F Tag 332 for medication errors occurring during self-administration in a nursing home, since the error is being made by the patient and not by staff.

Question 3: Is it okay for a person in methadone treatment to be administered Remeron?

Yes, with caution. The only drug interaction between methadone (Methadose®) and mirtazapine (Remeron®) is an increased sedative effect, so the staff should monitor the resident for increased drowsiness. However, an individual in methadone treatment programs may have other mental health issues where the use of mirtazapine may not be the best choice for treating that person. The treatment team for this individual should discuss all options and develop a plan that best fits this individual and then they should monitor and consistently communicate with each other.

Pharmacy Consultant Comments:

I would like to thank Ryan Bender for his work in July and August. He has developed a training program about pending pharmacy standards for sterile compounding that I will present this fall for hospital, home health and hospice surveyors, including engineers. He has developed the majority of the content of this newsletter, participated in a long-tern care survey, worked on the Cancer Drug Repository rule, worked on some Medicaid projects and other projects as they came up. Ryan has contributed to the BQA's and my own ongoing learning. I believe the BQA' s relationship with the UW-Pharmacy school and students like Ryan will continue to benefit BQA into the future. I want to thank the department leadership for their support in this initiative.

References are available upon request.